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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,350	07/12/2001	Linda L. Roman	050320-1080	1556
24504	7590	01/18/2006		
THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948			EXAMINER GOTTSCALK, MARTIN A	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,350	ROMAN ET AL.	
	Examiner	Art Unit	
	Martin A. Gottschalk	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/24/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-24 have been examined.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Iliff (US PG Pub# 2001/012913, hereinafter Iliff).

- A. As per claims 1 and 17, Iliff discloses a method for qualifying and selecting patients to be included in a technology-assisted disease management (TADM) system, comprising the steps of:

receiving an input associated with the patient (Iliff: [0130], reads on "...obtains health measurements for the patient...");

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assessing said input using a global goal module (Iloff: [0130], reads on analyzes health state using a Correlation Assessment function and Critical Curve Assessment function...". Note from the same passage that at least the Critical Curve is used by the "DMM", i.e. the Disease Management Module, which the Examiner considers to be a type of global goal module.) that is capable of defining the goals of the organization (Iloff: [0120], last sentence of the paragraph); and

determining if said input is a qualified input based upon said assessment (Iloff: [0131], i.e. the patient's health measurements are assessed, and then based on the assessment, it is determined whether the measurements are qualified so as to refer the patient for human medical attention or for further automated assessment, e.g. proceeding to the diagnostic module), where the patient associated with said qualified input is included in the TADM system (Iloff: [0122]).

B. As per claims 2 and 9, Iliff discloses the method of claim 1, further comprising the step of assessing said input

using a patient scoring module that is capable of providing the score of said input (Iloff: [0130], reads on "...encodes symptom descriptions using a PQRST Array, and calculates various relevant health counts...").

C. As per claim 3 and 10, Iliff discloses the method of claim 1, further comprising the step of assessing said input

using an intervention goals and outcome module (Iliff: [0131]-[0132]).

D. As per claims 4 and 18, Iliff discloses a method for qualifying and selecting patients to be included in the technology-assisted disease management (TADM) system, comprising the steps of:

receiving an input associated with the patient (Iliff: [0087] reads on "...prompting for a patient identification number...");

assessing said input using at least one qualifying module, said qualifying module having at least one predetermined parameter (Iliff: [0097], assessing reads on "...verifies the patient's identification", i.e. verifies PIN number, see [0087]; qualifying module reads on Fig. 4A, item 200).

determining if said input is a qualified input based upon said assessment (Iliff: [0097. The Examiner considers a verified PIN number to be a form of qualified input.]);

E. As per claims 5 and 19, Iliff discloses the method of claim 4, further comprising the steps of:

re-evaluating a non-qualified input (Iliff: [0098]); and

determining if said non-qualified input is a re-evaluated qualified input, where the patient associated with said re-evaluated qualified input is included in the TADM system (Iliff: [0099]-[0105]. The Examiner considers information obtained through “the assisted patient login process 212,” to be a type of non-qualified input and re-evaluated qualified input – i.e. the assistant is not qualified originally by the patient login process 200, but is re-evaluated and qualified as an assistant. Just as a patient provides a PIN, an assistant provides an AIN [0087] to be determined as a qualified assistant).

F. As per claim 6, Iliff discloses the method of claim 4, wherein the of step of assessing said input using at least one qualifying module further includes the step of

assessing said input using a global goal module (Iliff: [0130]. The Examiner notes that following login, the patient provides further input, reads on “health measurements,” which is assessed, reads on “...analyzes health state using a Correlation Assessment function and Critical Curve Assessment function...”. Note from the same passage that at least the Critical Curve is used by the “DMM”, i.e. the Disease Management Module, which the Examiner considers to be a type of global goal module, see also Iliff: [0120], last sentence of the paragraph).

G. As per claim 7, Iliff discloses the method of claim 6, wherein the of step of assessing said input using said global goal module further includes the step of

assessing said input using a patient category focus module (Iliff: [0138]. The Examiner considers the modules and tasks associated with "HEALTH ASSESSMENT" to be examples of using a patient category focus module).

H. As per claim 8, Iliff discloses the method of claim 6, wherein the step of assessing said input using said global goal module further includes the step of

assessing said input using an organizational category focus module (Iliff: [0135]-[0137]. The Examiner considers the functions performed in the "OPEN SESSION" to be a form of using an organizational category focus module. For example confirming patient registration, loading existing patient data, and creation of the Disease Management Order for storing session results are tasks with an organizational focus.).

I. As per claim 11, Iliff discloses the method of claim 4, further comprising the step of

selecting monitoring equipment based on said assessment of said input (Iliff [0188]. The Examiner notes that therapy for many chronic diseases such as diabetes includes monitoring the condition and can involve equipment such as a blood glucose

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monitor in the case of diabetes. Thus the selection of therapies offered to the patient in the cited passage would include monitoring equipment, depending on the condition being addressed.).

J. As per claims 12 and 20, Iliff discloses the method of claim 4, further comprising, the steps of:

receiving a qualified outcome input associated with the patient outcome of being included in the TADM system (Iliff: [0186]. The Examiner considers patient decisions concerning the outcome of side effect minimization, such as the one cited for a cancer patient, to be a form of the system receiving a qualified outcome input, the qualification being the fact that the input relates to side effect minimization);

assessing said outcome qualified input to determine if it is unsatisfactory, said determination based upon the patient outcome after being included in the TADM system (Iliff: [0185], reads on “....responses to treatment...are a matter of trial and error...”, i.e. if the current response to treatment – i.e. outcome - is assessed to be unsatisfactory, a change is made); and

resetting at least one of said parameters if said qualified outcome input is determined to be unsatisfactory (Iliff: [0185], reads on, “Therapy parameters that can be

changed include drug class...").

K. As per claims 13, 15, and 14 (system); and claims 21-23 (computer readable medium), they are system and computer readable medium claims respectively, which repeat the same limitations of claims 4, 5, and 12, the corresponding method claims, as collections of elements and logic respectively, as opposed to a series of process steps. Since the teachings of Iliff disclose the underlying process steps that constitute the methods of claims 4, 5, and 12, it is respectfully submitted that they provide the underlying structural elements and logic that performs the steps as well. As such, the limitations of claims 13, 15, and 14; and claims 21-23 are rejected for the same reasons given above for claims 4, 5, and 12 respectively.

L. As per claims 16 and 24, they are system and computer readable medium claims respectively, which repeat the same limitations of claim 1, the corresponding method claim, as collections of elements and logic respectively, as opposed to a series of process steps. Since the teachings of Iliff disclose the underlying process steps that constitute the methods of claim 1, it is respectfully submitted that they provide the underlying structural elements and logic that performs the steps as well. As such, the limitations of claim 16 and 24 are rejected for the same reasons given above for claim 1.

Conclusion

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4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art disclose automated methods of patient assessment and case management (US PG Pub#s 2002/0188182 and 2002/0069089).


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin A. Gottschalk whose telephone number is (571) 272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MG
09/02/2005


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER